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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/634,772 | 08/06/2003 | Akihiko Kandori | ASA-1144 | 6846 |

24956 7590 03/21/2007
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ALEXANDRIA, VA 22314

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| EXAMINER |
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CHENG, JACQUELINE

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| ART UNIT | PAPER NUMBER |
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3768

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/21/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/634,772

Applicant(s)

KANDORI ET AL.

Examiner

Jacqueline Cheng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>8/6/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claim 1** is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: how the first template waveform is generated. As the claim is currently written, the first template waveform is generated from a waveform from which the magnetic field waveform generated by said maternal heart has been removed (hereinafter maternal heart removed waveform). Which means when a cross correlation of the template waveform and the maternal heart removed waveform will always equal a 1.0 correlation. This is so because the first template waveform, generated from the maternal heart removed waveform, is the same thing as the maternal heart removed waveform.

3. **Claim 2** is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: how the second template waveform is generated. It is not disclosed how the second template waveform is generated, only that it is from the maternal heartbeat.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1, 4 and 6** are rejected under 35 U.S.C. 103(a) as being unpatentable over

Kandori'262 (US 6,269,262 B1) in view of Holls (US 5,372,139) further in view of Sternnickel (US 2004/0260169 A1). Kandori'262 (US 6,269,262) discloses the base elements of a means for shielding external magnetic fields, a bed, a plurality of SQUID magnetometers, a cryostat, a drive circuit, a processing unit, and a display unit (abstract). These are the base elements of most SQUID devices, and so therefore a very well known in the art and obvious to have and/or combine with any SQUID using method or apparatus such as combining it with the methods of Holls. Although Holls does not explicitly disclose using a SQUID device with his method, it would be obvious to one skilled in the art to do so, as it is obvious to one skilled in the art to use a SQUID device to obtain fetal heartbeats, for example as shown in Sternnickel (paragraph 0005, 0011, 0088, 0103). In Holls' method of obtaining a fetal heartbeat a plurality of electrodes are placed about the periphery of the mother to detect a substantially pure maternal heartbeat and to detect a composite mixed maternal and fetal heartbeat (abstract). The maternal heartbeat can be removed from the mixed heartbeat waveform to obtain a first template waveform of a fetal heartbeat. This fetal heartbeat can then be post processed by filters to improve the signal to noise ratio (col. 7 line 35-60) and by methods that are used upon the maternal heartbeat waveform (col. 4 line 44-48). So although Holls does not explicitly disclose post-processing the fetal heartbeat

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through sum-averaging and cross correlations, Holls does disclose doing this method with the maternal heartbeat to get the most accurate maternal signal to remove from the raw mixed waveform. Therefore it would be obvious to use this method upon both the maternal heartbeat and the fetal heartbeat to improve the signal to noise ratio (through the sum-averaging, providing the applicant's intended meaning of the "template waveform" in both claims 1 and 2), as well as the cross-correlation of the average (template) waveform with both heartbeat waveforms. A peak detection of the waveform, which can be performed on the cross-correlation waveform can be used to determine the fetal (or maternal) complex time locations, which then can be displayed (col. 3 line 40-50, col. 4 line 53-56).

6. **Claims 2, 3 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kandori'262 in view of Holls in view of Sternnickel further in view of Deans (US 5,666,959). Kandori'262, Holls and Sternnickel disclose most of what is claimed as described above except for baseline correcting process. Deans discloses that removal of baseline wander (or baseline correcting) is well known in the art of determining fetal complexes (col. 3 line 24-26, col. 4 line 65- col. 5 line 55). It would be obvious to combine these patents and correct the baseline of Holls in order to further the utility and accuracy of the outcome of the fetal complex of Holls.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,751,498 B1 to Greenberg.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596.

The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC


BRIAN L. CASLER
SUPERVISOR/ PATENT EXAMINER
TECHNOLOGY GROUP 8/20